



EXPRESS MAIL NO.: ED 701 987 828 US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Application of: | Michael Hope and Wendi Rodriguez | Confirmation No.: | 7809 |
| Serial No.: | 09/992,107 | Art Unit: | 1615 |
| Filed: | November 5, 2001 | Examiner: | Gollamudi S. KISHORE |
| For: | LIPOSOME COMPOSITIONS AND METHODS FOR THE TREATMENT OF ATHEROSCLEROSIS | Attorney Docket No: | 10173-072-999 (371855-999067) |

TERMINAL DISCLAIMER

MAIL STOP AF
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

The University of British Columbia, having a place of business in Vancouver, Canada (hereinafter the "Assignee"), represents that it is the Assignee of the above-identified application and of U.S. Patent No. 6,139,871. The assignment of U.S. Patent No. 6,139,871, which is the grandparent of the above-identified patent application, was recorded on May 9, 1994 at Reel 6983, Frame 6983 (the Assignment was recorded in parent application Serial Number 08/206,415). Copy of the Assignment is attached to this Terminal Disclaimer. Also attached is a copy of the Statement under 37 CFR 3.73(b) for the immediate parent of the application Serial No. 09/992,107.

The Assignee hereby disclaims the terminal part of any patent granted on the present application which would extend beyond the expiration date of U.S. Patent No. 6,139,871.

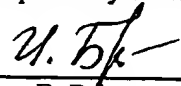
The Assignee hereby agrees that the above-identified application shall be enforceable only for and during such period that the legal title to the corresponding patent shall be the same as the legal title to U.S. Patent No. 6,139,871, this agreement is to run with any patent granted on the above-identified application and is to be binding upon the grantee, its successors or assigns.

In making the above disclaimer, petitioner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of U.S. Patent No. 6,139,871, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. 1.321, has all claims canceled by a reexamination certificate, is reissued, or is otherwise terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

The undersigned is empowered to act on behalf of and as a representative and petitioner of the Assignee in this matter.

Respectfully submitted,

Date: December 22, 2004


By: Irina E. Britva Reg. No. 50,498
for: Anthony M. Insogna Reg. No. 35,203

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claimed composition having liposomes of such mean diameter much less with the claimed Guassian distribution, and Liu can be said to be outside the claim scope as it is not blank liposomes as claimed.

Although there is no motivation to combine the teachings of Williams (1984 or 1986) with the teachings of Liu, if combined, the combination clearly teaches small liposomes, *i.e.* teaches away from the invention as claimed. There is no disclosure in Liu of blank liposomes of the proper size nor a suggestion of pharmaceutically acceptable liposomes of a size larger than in Williams.

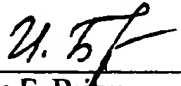
Additionally, Williams teaches a significant increase in LDL or esterified cholesterol levels in four hours after SUVs infusion (*see* Williams 1986, Fig. 2A, the peak labeled "P1" [LDL] at four hors ["t = 4h"]). The Office argues that the examination of the mentioned data in Williams did not reveal a statistically significant difference between values for the controls and the liposomes. Applicants respectfully disagree and submit that the experimental data in Williams corresponding to Fig. 2A, t = 4h, the peak labeled "P1" shows a dramatic (and surely statistically different) increase in the LDL levels. Thus, Williams 1986 not only discloses liposomes that are smaller than those that presently claimed but also teaches liposomes that cause an increase in LDL level after administration. As such, the reference teaches away from the present invention claiming that the liposomes are effective in promoting cholesterol efflux without causing a substantial increase in LDL or esterified cholesterol levels. Accordingly, Williams (1984 or 1986) in view of Liu does not render the instant claims obvious. Therefore, it is respectfully requested that the rejection be withdrawn.

CONCLUSION

Entry of the foregoing amendments and remarks is respectfully requested. No other fee than the extension of time fee is believed to be due with this Reply. However, if any other fee is required, please charge the fee to Deposit Account No. 503013. In view of the above remarks and amendments, it is submitted that the presently pending claims are in form for allowance and early action to that end is requested. If any issues remain, the Examiner is requested to telephone the undersigned at (858) 314-1130.

Respectfully submitted,

Date: December 22, 2004


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